Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2006 list were published in the Federal Register in February 2006.

New Approvals

NADA Number: 141-253

Trade Name:	Equioxx® Oral Paste
Ingredients:	Firocoxib
Sponsor:	Merial Limited
Approval Date:	December 30, 2005
Status:	Prescription only
Route:	Oral
Species:	Equine
Drug Form:	Paste
Concentration:	Each milligram of paste contains 0.82 milligram firocoxib
Indications:	For the control of pain and inflammation associated with osteoarthritis.
Patent number:	5,981,576 Expiration date: October 9, 2016
	6,020,343 October 9, 2016
Exclusivity:	3 years

21CFR 520.930

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-007

Trade Name:	Drontal® Plus Taste Tabs®
Ingredients:	Praziquantel, pyrantel pamoate, and febantel
Sponsor:	Bayer HealthCare LLC
Approval Date:	January 12, 2006

This application provides for the use of a flavored chewable tablet for the removal of several internal parasites in dogs. This supplemental approval qualifies for THREE (3) years of marketing exclusivity.

21CFR 520.1872

NADA Number: 141-220

Trade Name:	Cydectin®
Ingredients:	Moxidectin
Sponsor:	Fort Dodge Animal Health Division of Wyeth
Approval Date:	January 10, 2006

This application provides for use of an injectable moxidectin solution in cattle for the treatment and control of an additional three species (*Cooperia pectinata*- Adult, *Cooperia spatulata*- Adult, *Nematodirus helvetianus*- Adult) of internal parasites and an additional three life stages (*Trichostrongylus colubriformis*- Adult, *Ostertagia ostertagi*- L_4, *Trichostrongylus axei*- L_4) of previously approved internal parasites. This supplemental approval qualifies for THREE (3) years of marketing exclusivity.

21CFR 522.1450

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-040

Trade Name: Celerin™
Ingredients: Estradiol benzoate
Sponsor: PR Pharmaceuticals, Inc.
Approval Date: January 19, 2006

This application provides for subcutaneous injection, in the ear only, of a suspension implant of estradiol benzoate microspheres for increased rate of weight gain in suckling beef calves. It also adds the indication for use for increased rate of weight gain in steers fed in confinement for slaughter, previously approved at a lower dose, to the higher approved dose.

21CFR 522.841

Suitability Petition Action

Number: 06P-0060/CP1
Sponsor: Macleod Pharmaceuticals, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, Phenylzone® Paste, Schering-Plough Animal Health Corp., NADA 116-087 by the following characteristics: The generic product will have a different dosage form, granules, whereas the pioneer product is a paste.
Action: Filed February 1, 2006.

Notice(s)

The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (171) entitled ``Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles", [Docket No. 2004D-0283]. This guidance describes the procedures that the agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

Submit written or electronic comments on agency guidances at any time. Written comments on this guidance should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance via the Internet at http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the guidance and the docket number found in brackets above.

Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

For further information contact: Marilyn Martinez, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7577, e-mail: marilyn.martinez@fda.hhs.gov.

The Food and Drug Administration (FDA) is canceling the meeting on the Animal Drug User Fee Act scheduled for February 24, 2006. This meeting was announced in the Federal Register of December 28, 2005 (70 FR 76851). FDA will continue to seek public comments relative to the program's overall performance and reauthorization as directed by Congress. FDA will publish another notice in the Federal Register announcing any plans for rescheduling the public meeting.

Written comments may be submitted at any time and should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

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